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Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority Pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five jears. These addenda represent an updated literature search current as of 1988, plus additional information form Agency files and Program Offices. This addendum is to update the existing Ambient Water Quality Criteria Document for Toxaphene.

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OFFICE OF WATER REGULATIONS
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PREFACE

Under the 1977 Clean Water Act, Congress mandated the U.S. Environmental Protection Agency to develop ambient water quality criteria for 129 priority pollutants. These criteria were published in 1980. Under Section 304(a)(1) of the Clean Water Act as amended in 1987, the U.S. EPA is mandated to re-evaluate and update these criteria every five years. These addenda represent an updated literature search current as of 1988, plus additional information from Agency files and Program Offices. The first draft of this addendum was prepared by Syracuse Research Corporation under contract no. 68-C8-0004.

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LIST OF ABBREVIATIONS

BCF	Bioconcentration factor
CRAVE	Carcinogen Risk Assessment Verification Endeavor
DWEL	Drinking water equivalent level
HA	Health advisory
MCL	Maximum contaminant level
LOAEL	Lowest-observed-adverse-effect level
NOAEL	No-observed-adverse-effect level
PEL	Permissible exposure limit
ppm	Parts per million
RMCL	Recommended maximum contaminant level
STEL	Short-term exposure level
TLV	Threshold limit value
TWA	Time-weighted average

INTRODUCTION

Under Section 304(a)(1) of the Clean Water Act of 1977 as amended in 1987, the U.S. EPA is required to publish criteria for water quality accurately reflecting the latest scientific knowledge regarding the effects on health and welfare that may occur from the presence of pollutants in any body of water, including groundwater. In accordance with the 1977 act, Ambient Water Quality Criteria Documents (AWQCDs) were developed in 1980 for 65 toxic pollutants or classes of pollutants listed under Section 307(a)(1).

These addenda are intended to serve as an update of the original AWQCDs. The addenda provide the Agency with the latest scientific assessments of potential health hazards associated with these pollutants and serve as guidelines for modifying the current (1980) AWQCDs.

The human health criteria in these addenda are based on Agency verified risk assessment values when available. These values consist of reference doses (RfD) for those chemicals believed to be systemic toxicants (i.e., do not induce cancer) and cancer risk factors for those thought likely to cause cancer in humans. The verification process consists of a review and consensus of risk assessment values provided by an Agency workgroup consisting of scientists from each of the major Agency offices. Assessments for noncarcinogens are verified by the RfD workgroup and those for carcinogens are verified by the Carcinogen Risk Assessment Verification Endeavor (CRAVE) workgroup. If such values are not available, the criteria are based on the most recent Agency health assessment. In the absence of any appropriate Agency value, RfD values or cancer risk factors are derived by current Agency methods if adequate new data are available, and criteria are recommended based on the proposed RfD or risk factor.

The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of the daily exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. The RfD is derived by dividing a NOAEL or LOAEL for subchronic or chronic exposure by standard uncertainty factor(s) times an additional uncertainty factor:

$$RfD = \frac{\text{NOAEL or LOAEL}}{\text{UF(s)} \times \text{UF}}$$

The standard uncertainty factors are applied to reflect the various types of data used to estimate RfDs. An uncertainty factor of 10 is used to account for variations in human sensitivity when extrapolating from valid human studies involving long-term exposure of average, healthy subjects. An additional 10-fold factor is used for each of the following: to extrapolate from long-term animal studies to the case of humans, to extrapolate from subchronic animal studies to chronic exposure, and to extrapolate from a LOAEL to a NOAEL. An additional uncertainty factor of >0-10 may be applied to reflect professional assessment of the uncertainties of the study and data base not explicitly addressed by the standard uncertainty factors (i.e., completeness of the overall data base). The default value for the additional uncertainty factor is 1.

In assessing the carcinogenic potential of a chemical, the U.S. EPA classifies the chemical into one of the following groups according to the degree of evidence in epidemiological studies and animal studies: Group A - Human Carcinogen; Group B - Probable Human Carcinogen [limited evidence in humans with or without sufficient evidence in animals (Group B1) or inadequate evidence in humans with sufficient evidence in animals (Group B2)]; Group C - Possible Human Carcinogen (limited evidence of carcinogenicity in animals in the absence of human data); Group D - Not Classifiable as to

Human Carcinogenicity (inadequate or no evidence); Group E - Evidence of Noncarcinogenicity for Humans. Quantitative carcinogenic risk assessments are performed for chemicals in Groups A and B, and on a case-by-case basis for chemicals in Group C. Upper-bound cancer unit risks (slope values) are estimated through the use of mathematical extrapolation models. Most commonly for animal data, the linearized multistage model with a 95% upper confidence limit is used to provide a low-dose estimate of cancer risk. The cancer risk is characterized as an upper-limit estimate (i.e., the true risk to humans, while not identifiable, is not likely to exceed the upper-limit estimate and in fact may be lower). Alternative risk models to the multistage model, such as the one-hit, Weibull, Logit or Probit model, are available and may be used when the evidence indicates that they may be more appropriate. In the absence of such evidence, the Agency recommends the linearized multistage model to provide consistency of approach and an upper-bound on the potential carcinogenic risk. In the case where human data are used for quantitative risk assessment, an upper-bound estimate rather than a 95% upper-bound estimate is used when low-dose linearity is assumed.

In the development of this Addendum to the AWQCD on toxaphene, recent Agency assessments have been consulted. A computerized literature search was conducted to cover studies published more recently than the latest Agency assessment (i.e., published in 1987 to 1988). New key studies have been evaluated.

REVIEW OF NEW DATA

Toxicologic/Carcinogenic Effects

Recent U.S. EPA (1987a,b,c) assessments regarding the toxicologic and carcinogenic effects of toxaphene do not provide any additional information for risk assessment. No new studies were located in the literature searches for toxaphene.

Bioconcentration Factor (BCF)

In the 1980 AWQCD (U.S. EPA, 1980), the mean BCF value for toxaphene after normalization to 1% lipids was 4372. In 1982, this figure was recalculated to be 6150 (U.S. EPA, 1982) with a weighted average BCF value for toxaphene. These values are currently undergoing Agency review. When this review has been completed, pertinent new information will be incorporated.

QUANTIFICATION OF EFFECTS

The U.S. EPA (1980) developed ambient water quality criteria for toxaphene corresponding to incremental increases in lifetime cancer risk of 10^{-5}, 10^{-6} and 10^{-7} of 7.1, 0.71 and 0.07 ng/ℓ, respectively, for water and fish and shellfish consumption. Because of a change in the BCF (see previous section), the U.S. EPA (1982) revised these values to 5.1, 0.51 and 0.05 ng/ℓ for water and fish and shellfish consumption, and 5.2, 0.52 and 0.05 ng/ℓ for fish and shellfish consumption only. U.S. EPA (1987d), however, lists the original criteria rather than the revised values. These criteria are based on the incidence of hepatocellular carcinomas in B6C3F1 mice (54/sex/group) receiving 0, 7, 20 or 50 ppm (0, 0.91, 2.6 or 6.5 mg/kg/day) toxaphene in the diet for 18 months (Litton Bionetics, Inc., 1978). There was a dose-related and statistically significant increase in the incidence of hepatocellular carcinomas and neoplastic nodules in the males (10/53, 11/54, 12/53 and 18/51 for the various doses, respectively), as well as a nonsignificant increased incidence in the females. A q_1^* of 1.131/mg/kg/day was derived from the data for the male mice.

A study that supports this q_1^* was performed by NCI (1979) and was reviewed in U.S. EPA (1980). Osborne-Mendel rats (50/sex/group) received toxaphene in the feed at TWA dosages of 556 ppm and 1112 ppm in the males and 540 ppm and 1080 ppm in the females for 80 weeks, followed by observation for 28-30 weeks. The control groups had 10 rats/sex. The incidences of thyroid follicular cell adenoma in the control, low- and high-dose groups were 1/7, 7/41 and 9/35 in males, and 0/6, 1/43 and 7/42 in females, respectively. The incidences in treated rats were statistically increased in the high-dose group when compared with pooled controls.

B6C3F1 mice (50/sex/group) received TWA doses of 0, 99 or 198 ppm toxaphene in the feed for 80 weeks, followed by a 10- to 11-week observation period. The high- and low-dose males and females showed a statistically significant and dose-related increase in hepatocellular carcinomas (NCI, 1979).

The U.S. EPA has classified toxaphene in Group B2, based on increased incidence of hepatocellular tumors in mice and thyroid tumors in rats (U.S. EPA, 1987c). IARC (1979) places toxaphene in Group 2B.

U.S. EPA (1987c) has verified the q_1^* (slope factor) of 1.131/mg/kg/day (rounded to 1.1/mg/kg/day) originally derived in U.S. EPA (1980). Using the unrounded slope factor of 1.131/mg/kg/day, and assuming 70 kg body weight and a daily intake of 2 ℓ of water and 6.5 g of fish and shellfish with a weighted average BCF for toxaphene of 18,450 (U.S. EPA, 1982), the new criteria for toxaphene in ambient water are as follows:

Exposure Assumptions (per day)	Risk Levels and Corresponding Criteria (ng/ℓ)				
	0	10^{-7}	10^{-6}	10^{-5}	10^{-4}
2 ℓ of drinking water and consumption of 6.5 g of fish and shellfish	0	0.051	0.51	5.1	51
Consumption of fish and shellfish only	0	0.052	0.52	5.2	52

EXISTING STANDARDS AND CRITERIA

U.S. EPA (1987c) has verified a slope factor for oral exposure of 1.1/mg/kg/day, a corresponding unit risk factor of 3.2×10^{-5}/µg/ℓ and a Group B2 classification for toxaphene (see previous section).

U.S. EPA (1987a) has derived a 1-day HA for a child of 0.5 mg/ℓ based on a NOAEL of 5 mg/kg (single oral dose) for convulsions in dogs (Lackey, 1949). The 10-day HA for a child is 0.04 mg/ℓ based on a LOAEL of 4 mg/kg/day (repeated oral doses) for liver and kidney effects in dogs (Lackey, 1949). Longer-term HAs and a DWEL were not derived because of inadequate data. Using the q_1^* of 1.131/mg/kg/day (see previous section), exposure levels of 3.1, 0.31 and 0.031 µg/ℓ were calculated to correspond to risk levels of 10^{-4}, 10^{-5} and 10^{-6}, respectively (U.S. EPA, 1987a).

The MCL for toxaphene in drinking water is 0.005 mg/ℓ and the proposed RMCL, based on carcinogenicity, is 0 (U.S. EPA, 1985).

The current OSHA (1985) standards list toxaphene under chlorinated camphene, and give a PEL of 0.5 mg/m³ with a skin notation. The ACGIH (1987) also gives a skin notation for the TWA-TLV of 0.5 mg/m³ and the STEL of 1 mg/m³.

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